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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09 394,204	09/10/1999	DAVID M. STERN	52209-A-PCT-	3891

7590 04/10/2002

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NEW YORK, NY 10036

EXAMINER

HAYES, ROBERT CLINTON

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 04/10/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
09/394,204

Applicant(s)  
Stern et al

Examiner  
Robert C. Hayes, Ph.D.

Art Unit  
1647



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Jan 11, 2002
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above, claim(s) 1-19 and 23-25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 20 and 21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claims 1-25 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some\* c) ☐ None of:

- ☐ Certified copies of the priority documents have been received.
- ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_
- ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

15) ☒ Notice of References Cited (PTO-892)

16) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 4 & 9

18) ☐ Interview Summary (PTO-413) Paper No(s).

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

Art Unit: 1647

## **DETAILED ACTION**

### ***Election/Restriction***

1. Applicant's election with traverse of Group V (claims 20-21) in Paper No. 10 is acknowledged. The traversal is on the ground(s) that all groups are "related" and therefore should be rejoined. This is not found persuasive because each of the separate groups are distinct because they have acquired a separate status in the art as shown by their different classification, they are directed toward patentably distinct products, or are directed to methods with different goals, starting materials and/or method steps. It is again pointed out that there is a proper distinction between these groups, since each product is not required in order for the other to exist. Therefore, because these inventions are distinct for the reasons given above and in the previous Office action, and the non-coextensiveness of the search and examination for each group would constitute an undue burden on the examiner to search and consider each of these separable groups, the requirement is still deemed proper. The requirement is still deemed proper and is therefore made FINAL.

Claims 1-19 & 22-25 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 10.

This application contains claims 1-19 & 22-25 drawn to an invention nonelected with traverse in Paper No. 10. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Art Unit: 1647

***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 20-21 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a binding assay using the specific purified ERAB polypeptide of SEQ ID NO 2 and the amyloid-beta polypeptide structurally described on pages 1-2 of the specification, does not reasonably provide enablement for any method in which the required components necessary to practice the method are structurally and functional uncharacterized (i.e., as it relates to generic uncharacterized ERAB polypeptides). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The name "ERAB polypeptide" (as it relates to how it is defined on pages 14-17 of the specification) does not sufficiently characterize and enable the polypeptides that are required to practice the instant invention, because the inclusion of any "variant or portion thereof", or "insertions, deletions and substitutions thereof", or any biologically functional equivalent protein, within the definition of a ERAB polypeptide sets forth little structural and functional characteristics. In contrast, the specification does not teach which particular amino acids are critical for any ERAB protein's function, nor how to distinguish such from any different polypeptide sequence that possesses none of the desired functions of the instant invention.

Art Unit: 1647

Moreover, random modifications, mutations, substitutions, additions, deletions or truncations of different ERAB-related polypeptides would be expected by the skilled artisan to result in generation of inactive proteins, and therefore, a method that does not work. For example, Rudinger states on page 3 that "it is impossible to attach a unique significance to any residue in a sequence. A given amino acid will not by any means have the same significance in different peptide sequences, or even in different positions of the same sequence". Rudinger further states on page 6 that "the significance of particular amino acid sequences for different aspects of biological activity cannot be predicted *a priori* but must be determined from case to case by painstaking experimental study". Therefore, the lack of guidance provided in the specification as to what minimal structural requirements are necessary for any ERAB protein's function that is a required component for knowing how to successfully make and use the instant method would prevent the skilled artisan from determining whether any modification or mutation to the specific human ERAB protein of SEQ ID NO: 2 could be made which retains the desired function of the instant invention, because any random mutation or modification manifested within such a ERAB protein would be predicted to adversely alter its biologically active 3-dimensional conformation, and therefore, a method that the skilled artisan would not know how to make and/or use, without undue experimentation to determine otherwise.

3. Claims 20-21 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP

Art Unit: 1647

§ 2172.01. The omitted steps are what the evaluation step recited in claim 20(c) entails. For example, amending claim 20(c), for example, to “[thereby evaluating] wherein when the amount of amyloid-beta peptide bound to ERAB polypeptide is decreased in the presence of said agent, the ability of the agent to inhibit binding of ERAB polypeptide to amyloid-beta peptide is determined”, may obviate this rejection.

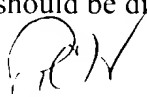
4. Claim 21 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for using improper Markush language. Elements within a Markush group are required to possess some structural similarity (e.g., be classified within the same class), which clearly is not the situation here. For example, nucleic acids are class 536/23.1, while proteins are class 435.350, while the class of small molecules is unknown. See M.P.E.P. 2173.05(h).


### *Conclusion*

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (703) 305-3132. The examiner can normally be reached on Monday through Thursday, and alternate Fridays, from 8:30 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

  
Robert C. Hayes, Ph.D.  
March 28, 2002

  
GARY L. KUNZ  
SUPERVISORY PATENT EXAMINER  
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